



# **DRUG ALERT**

## **CLASS 4 MEDICINES DEFECT INFORMATION**

**Caution in Use**  
**Distribute to Hospital Pharmacy Level**

Date: 14<sup>th</sup> September 2016

EL (16)A/13

Our Ref: MDR 037-09/16

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Dear Healthcare Professional,

### **EcoLab**

#### **Klerpack BD Syringe Multi-Pack**

Ecolab are recalling batches of Klerpack BD Syringe Multi-Pack as the sterile packaging may contain small holes in the film of the pouch. If holes are present, the package integrity is compromised and there is a risk that the syringe may no longer be sterile. The affected syringe products and batches are listed in Appendix 1 (Ecolab Field Safety notice).

The objective of this Drug Alert is to make users of the syringes aware of the Field Safety Notice in order to:

- Quarantine affected stock of the syringes
- Perform a local risk assessment for unexpired medicinal products produced using the affected batches of syringes

The local risk assessment should take into account the following factors:

- Specific use of the syringe (such as use during the manufacturing/compounding process and/or the final closed container system)
- Nature of the medicinal product (such as expiry period; susceptibility to microbiological proliferation, or any inhibitory effect)
- Route of administration and patient population
- Likelihood of medicinal product shortage (is replacement stock or an alternative product available?); impact of shortage on patients
- Ecolab data indicates a high likelihood of syringe packaging being compromised. The holes cannot be detected visually.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully  
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